General

Guideline Title

Heart failure in adults.

Bibliographic Source(s)

Pinkerman C, Sander P, Breeding JE, Brink D, Curtis R, Hayes R, Ojha A, Pandita D, Raikar S, Setterlund L, Sule O, Turner A. Heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jul. 94 p. [190 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2011 Aug. 110 p.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report— July 2013 . In addition, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This document is in transition to the GRADE methodology. Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available systematic reviews in literature searches.
- All existing Class A (randomized controlled trials [RCTs]) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE (see below in the "Definitions" section).
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

The recommendations for the management of heart failure (HF) in adults are presented in the form of an algorithm with 17 components, accompanied by detailed annotations. Algorithms are provided in the original guideline document at the ICSI Web site for Heart Failure in Adults. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (Low Quality, Moderate Quality, High Quality, Meta-analysis, Systematic Review, Decision Analysis, Cost-Effectiveness

Analysis, Guideline, and Reference) ratings and key conclusion grades (I-III, Not Assignable) are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- Evaluate patients presenting with heart failure for exacerbating and underlying causes including coronary artery disease, hypertension, valvular disease, and other cardiac and non-cardiac causes. *(Annotation #2; Aim #3)*
- Studies show that the distinction between systolic dysfunction and preserved systolic function is important because the choice of therapy may be quite different and some therapies for systolic dysfunction may be detrimental if used to treat preserved systolic function. *(Annotation #2; Aim #3)*
- Daily weights are critical for managing heart failure and early detection of increases in fluid retention. Patients should call their provider about a two-pound or greater weight gain overnight or a five-pound or greater weight gain in a week. Patients can expect the clinician to assess symptoms, adjust diuretics if appropriate, discuss dietary sodium compliance/restriction, review treatment plan, and recommend appropriate level of care (office visit, emergency department [ED], etc.) *(Annotation #14; Aim #4)*
- Unless specific contraindications exist, treat all patients with beta-blockers starting with a low dose and titrating upward. *(Annotation #13; Aim #2)*
- Treat all patients with left ventricular systolic dysfunction with angiotensin-converting enzyme (ACE) inhibitors (or angiotensin receptor blockers [ARBs] if intolerant) unless specific contraindications exist. *(Annotations #13; Aim #2)*
- Consider early specialty referral for patients with ischemia or those who are refractory despite optimal medical therapy. *(Annotation #10; Aim #3)*
- Brain natriuretic peptide (BNP) and N-terminal pro-B-type natriuretic peptide (NTproBNP) are useful in the diagnosis and prognosis of heart failure in patients with dyspnea of unknown etiology. *(Annotation #2; Aim #3)*
- For patients self-described as African Americans who have moderate-to-severe symptoms on optimal therapy with ACE inhibitors, beta-blockers, and diuretics, the combination of hydralazine and nitrates is recommended because the combination has resulted in significant benefit to the group in randomized controlled trials. *(Annotation #13; Aim #2)*

Heart Failure Algorithm Annotations

1. Patient Presents with Signs and Symptoms of Heart Failure (Excluding Acute Coronary Syndrome)
   Signs and Symptoms of Congestion

   - Dyspnea
   - Orthopnea
   - Paroxysmal nocturnal dyspnea (PND)
   - Cough (recumbent or exertional)
   - Abdominal or epigastric discomfort
   - Abdominal bloating (ascites)
   - Early satiety
   - Hemoptysis, frothy or pink-tinged sputum
   - Pedal/leg swelling
   - Weight gain (rapid)
   - Sleep disturbances (anxiety or air hunger)
   - Chest tightness or discomfort
   - Unexplained confusion, altered mental status, or fatigue
   - Nausea or anorexia
   - Dependent edema

   Signs and Symptoms of Poor Perfusion/Low Cardiac Output

   - Easy fatigability
   - Poor energy level or endurance
   - Decreased exercise tolerance
   - Cachexia
   - Muscle wasting or weakness
   - Nausea or anorexia
   - Early satiety
   - Weight loss, unexplained

- Malaise
- Impaired concentration or memory
- Sleep disturbance
- Altered mentation (somnolence, confusion)
- Resting tachycardia
- Daytime oliguria with recumbent nocturia
- Cool or vasoconstricted extremities
- Cheyne-Stokes respiration (with or without apnea)

See Appendix A in the original guideline document for the New York Heart Association (NYHA) Classification and American College of Cardiology/American Heart Association (ACC/AHA) Staging System Comparison.

2. Initial Evaluation/History and Physical/Laboratory Tests/Diagnostic Tests
   Recommendations

   - Clinicians must perform an initial evaluation to confirm a diagnosis of HF and identify an etiology/precipitating factor(s). The diagnosis of heart failure should not be a single diagnosis.
   - Consider consultation with cardiology during the initial evaluation and any time that it is felt appropriate in the ongoing management of heart failure patients.

   Questions to Determine Severity

   A. History
      Presenting Symptoms

      - Dyspnea/PND/orthopnea
      - Recent weight gain
      - Chest pain
      - Palpitations
      - Blood loss/causes of anemia
      - Recent fevers/viral infection
      - Cough/sputum production
      - Claudication
      - Exercise tolerance
      - Fatigue
      - Edema/ascites
      - Color changes

      Past Medical History

      - History of congestive HF
      - History of myocardial infarction (MI)
      - Hypertension/smoking/diabetes/hyperlipidemia
      - History/risk factors for thromboembolic disease
      - History of thyroid dysfunction
      - Recently postpartum (within the first month)
      - History of snoring/sleep apnea
      - Blunt chest injury
      - Rheumatic fever
      - Human immunodeficiency virus (HIV)
      - Bacterial endocarditis
      - Claudication
      - Screen for depression
      - Foreign travel

      Family History

      - Screen for family history of ischemic heart disease, HF, congenital heart disease, risk factors for athero-sclerotic cardiovascular disease (ASCVD) and HF

      Social History

- Smoking
- Alcohol use/abuse screen
- Drug abuse

Dietary History

- Salt and daily fluid intake
- Balanced diets

B. Physical Exam
   - Vital signs, including weight and height
   - Diaphoresis
   - Diminished peripheral pulse or bruit
   - Skin color: cyanosis, pallor, jaundice
   - Lower extremity edema in the absence of venous insufficiency
   - Elevated jugular venous pressure, positive hepato-jugular reflux
   - Heart rate: tachycardia, bradycardia/arrhythmias
   - Left lateral displacement of the point of maximal impulse (PMI)
   - Heart sounds: S3, S4, or murmur
   - Lungs: labored breathing, rales above the lower 25% of the lung that do not clear with cough
   - Abdomen: large, pulsatile, or tender liver or ascites

   [Guideline]

C. Initial Laboratory Evaluation
   - Initial
     - Complete blood count
     - Electrolytes (Na^+, K^+) and Cl^-, bicarbonate, Ca^{++}, Mg^{++} (if on diuretics)
     - Renal function (blood urea nitrogen [BUN], creatinine [Cr])
     - Liver function (aspartate transaminase [AST], alanine transaminase [ALT], alkaline phosphatase, bilirubin, total protein [T Prot], albumin)
     - Urinalysis
     - Sensitive thyroid-stimulating hormone (sTSH)
     - Prothrombin time/international normalized ratio (PT/INR)
     - NTproBNP or BNP
     - Tests for myocardial injury: troponin
   - Other Laboratory Evaluation
     - Ferritin/iron/total iron-binding capacity (TIBC)/macrocytic anemias
     - Lipid profile
     - Blood culture (if endocarditis suspected)
     - Lyme serology (if suspect bradycardia/heart block)
     - Connective tissue disease work up
     - HIV

   [Guideline]

   Role of BNP/NTproBNP in the Diagnosis and Management of Heart Failure

   BNP and NTproBNP assays have been found useful in the correct diagnosis of patients with dyspnea, especially when the patient has a history of pulmonary disease and/or cardiac disease. Since BNP and NTproBNP concentrations correlate positively with cardiac filling pressures, measurement of a low concentration makes it unlikely that dyspnea is due to cardiac dysfunction.

   Refer to the original guideline document for more details on the role of BNP and NTproBNP in the diagnosis and management of heart failure.

   [Low Quality Evidence]

   Cardiac Troponins in Heart Failure

   Newer methods of cardiac troponin (cTn) assay are more sensitive, and detectable levels of cTn are found in most patients with chronic heart failure. Multiple mechanisms, in addition to cardiac ischemia, have been proposed for the elevation of cTn in this

population. The end result of the different mechanisms results in worsening cardiac dysfunction and progression of heart failure.

Regardless of the heart failure population studied or the assay method, multiple studies have demonstrated the consistent association between cTn elevation and worse outcomes. Elevated cTn levels, therefore, identify a cohort of patients in the heart failure population who are at higher risk. Some of these patients may have ischemia as a factor and may be candidates for revascularization. Circulating cTn levels may also provide insight into the transition from a chronic compensated state to acute decompensated heart failure.

The work group recommends an initial determination of cTn for patients presenting to the hospital with acute heart failure. Troponin assessment can be used for immediate risk stratification and may also suggest acute coronary syndrome (ACS) as the underlying etiology, depending on other presenting features. In patients with initially elevated cTn levels, a repeat cTn measurement within 6 to 12 hours can help determine whether or not the kinetics of cTn change are more consistent with either ACS or acute decompensated heart failure. In ambulatory patients with heart failure, cTn measurement is a reasonable prognostic indicator. Persistently elevated cTn values in chronic heart failure patients should lead to consideration of more intensive medical therapy, as well as an evaluation for ischemic heart disease (if not already performed). *[Low Quality Evidence]*

D. Diagnostic Tests
   - Electrocardiogram
   - Chest radiograph
   - Assessment of ventricular function (echocardiogram, radionuclide ventriculography)
     - It is reasonable to reassess ejection fraction (EF) if the patient is clinically decompensated or after the patient has been titrated up to target doses of beta-blockers and ACE inhibitors.
   - Ischemia evaluation in patients with coronary artery disease (CAD) risk factors (stress test, angiography). Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Diagnosis and treatment of chest pain and acute coronary syndrome (ACS).

   An electrocardiogram (ECG) and a chest radiograph are fundamental parts of the initial evaluation for heart failure. In addition, the objective evaluation of ventricular performance is also a critical part for patients with suspected or known heart failure. Objective evaluation of left ventricular (LV) function is necessary because chest x-ray (CXR), ECG, and history and physical examination often fail to distinguish normal from low EF in patients with heart failure *[Low Quality Evidence]*.

E. Assess for Causative and Precipitating Factors
   Causes of heart failure can be classified as cardiac and non-cardiac. Refer to Tables 1 and 2 in the original guideline document for the salient features of the more common causes.

3. Unstable Signs and Symptoms Requiring Emergent Management?
   Recommendation:

   - Early triage should be performed to determine whether emergent or inpatient care is needed.

   Unstable symptoms may include:

   - Dyspnea: at rest/orthopnea (change from baseline), sudden onset of shortness of breath (SOB), worsening SOB, exertional dyspnea, gasping
   - Arterial oxygen saturation (SaO_2) less than 90%
   - Coughing up pink/frothy sputum
   - Dizziness or syncope
   - Chest pain
   - Systolic blood pressure (BP) less than 80 to 90 mmHg and symptomatic
   - Evidence of hypoperfusion (cyanosis, decreased level of consciousness, etc.)

4. Send to Hospital for Emergency Department or Inpatient Care
   Consider hospitalization in the presence or suspicion of heart failure with any of the following findings:

   - Clinical, laboratory, or electrocardiographic evidence of acute myocardial ischemia or infarction
   - Severe symptoms of heart failure refractory to outpatient therapy
   - Pulmonary edema or severe respiratory distress
   - Thromboembolic complications requiring interventions
   - Severe complicating medical illness (e.g., pneumonia, renal failure)
   - Management of clinically significant arrhythmias (hemodynamic effects)

- Anasarca (generalized edema)
- Inadequate social support for safe outpatient management
- Symptomatic hypotension or syncope
- Hyperkalemia

By definition, these patients are Stage C and D, NYHA Class III or IV. (See Appendix A in the original guideline document for the New York Heart Association Classification and ACC/AHA Staging System Comparison.) Heart failure should not be the final, stand-alone diagnosis. There should always be an associated etiology and/or contributing factor. The etiology of heart failure and the presence of exacerbating factors or other diseases that may have an important influence on management should be carefully considered in all cases.

5. Determine the Diagnosis of Heart Failure Using the Framingham Criteria Tool
   Diagnosis of heart failure requires the simultaneous presence of at least two major criteria or one major criterion in conjunction with two minor criteria.

   Major criteria:

   - Paroxysmal nocturnal dyspnea
   - Neck vein distention
   - Rales
   - Radiographic cardiomegaly (increasing heart size on chest radiography)
   - Acute pulmonary edema
   - S3 gallop
   - Increased central venous pressure (greater than 16 cm H_2O at right atrium)
   - Hepatojugular reflux
   - Weight loss greater than 4.5 kg in five days in response to treatment

   Minor criteria:

   - Bilateral ankle edema
   - Nocturnal cough
   - Dyspnea on ordinary exertion
   - Hepatomegaly
   - Pleural effusion
   - Decrease in vital capacity by one-third from maximum recorded
   - Tachycardia (heart rate greater than 120 beats/minute)

   Minor criteria are acceptable only if they cannot be attributed to another medical condition (such as pulmonary hypertension, chronic lung disease, cirrhosis, ascites, or the nephrotic syndrome).

   The Framingham Heart Study criteria *[Low Quality Evidence]* are 100% sensitive and 78% specific for identifying persons with definite heart failure.

8. Obtain Echocardiogram
   Recommendation:

   - Clinicians must determine whether ventricular dysfunction is systolic or diastolic, because therapies are different. Some therapies for systolic dysfunction may be harmful if used to treat preserved systolic function.

   In patients with heart failure symptoms, it is important to determine if they have left or right ventricular systolic dysfunction or preserved systolic function. One-third of patients has predominantly preserved systolic function, one-third has both systolic and diastolic dysfunction, and one-third has predominantly systolic dysfunction.

   The community prevalence of heart failure with preserved EF is high, and among these patients, most have preserved systolic function. Heart failure with preserved ejection fraction (HFPEF) has increased in prevalence over time. Patients with preserved ejection fraction (EF) are older, are more likely to be women, are less likely to be smokers or have a history of MI, and have a lower New York Heart Association class but have similar comorbidities.

   Studies show that the distinction between systolic dysfunction and diastolic dysfunction with preserved systolic function is important, because the choice of therapy may be quite different, and some therapies for systolic dysfunction may be detrimental if used to treat patients with primarily diastolic dysfunction *[Low Quality Evidence]*.

   Diastolic dysfunction of mild degree is commonly associated with systolic dysfunction, but isolated diastolic dysfunction may be seen with

left ventricular hypertrophy, myocardial ischemia, constrictive pericarditis or cardiac tamponade, or in the case of infiltrative diseases such as amyloidosis or in long-standing hypertension *[Moderate Quality Evidence]*.

Interpretation of Ventricular Function Testing

Heart failure is a clinical syndrome that correlates poorly with ejection fraction. Some patients may have symptoms based on systolic dysfunction (heart failure with reduced ejection fraction [HFREF]), while others have heart failure with diastolic dysfunction and preserved systolic function. Measurement of left ventricular (LV) function provides important prognostic information.

Objective assessment of LV function is necessary because CXR, ECG and history and physical often fail to distinguish normal from low EF in patients with heart failure.

Measurement Techniques

Both echocardiography and radionuclide ventriculography may be used to measure left ventricular performance. Both methods are reasonably accurate and reproducible for the assessment of systolic dysfunction, but may be influenced by operator technique and ventricular loading conditions. In general, it is appropriate to think of the EF measurement in an individual patient at a particular point in time as being an estimate with a range of ±5%. Reproducible and operator independent quantitative assessment of preserved systolic function is more difficult and may be influenced by changes in ventricular preload and afterload at the time of the test.

Measurements may vary with changes in the underlying disease process or with differences in systolic or diastolic ventricular loading conditions. Hence, they may change over time because of progression or regression of the underlying ventricular muscle dysfunction, and/or with changes in therapy, as well as the level of hydration at the time of measurement. It is reasonable to reassess ventricular function after interventions or when symptoms have changed significantly. Changes in ventricular function may imply a change in prognosis and may require changes in therapy.

Refer to the original guideline document for more information on measurement techniques of LV function.

11. Heart Failure Management
Treatment of Systolic Dysfunction

The cornerstone of treatment is the use of beta-blockers and ACE inhibitors. Certain beta-blocking medications have been shown to improve clinical symptoms and ventricular function in patients with systolic dysfunction.

Beta-blockers decrease hospitalizations and mortality, and have objective beneficial effect on measures of exercise duration.

ACE inhibitors prolong life in patients with heart failure symptoms and EF less than 35% and reduce symptom development in asymptomatic patients with EF less than 35% *[High Quality Evidence]*. There is also a mortality benefit in the use of ACE inhibitors in patients with recent myocardial infarction and asymptomatic EF less than 40% *[High Quality Evidence]*. ACE inhibitors slow disease progression, improve exercise capacity and decrease hospitalizations and mortality *[High Quality Evidence]*, *[Moderate Quality Evidence]*.

Patients who are intolerant of ACE inhibitors may benefit from the combination of hydralazine and nitrates. This treatment has been shown to improve survival compared to placebo but is less effective than ACE inhibition *[High Quality Evidence]*, *[Moderate Quality Evidence]*. ARBs are recommended for patients intolerant of ACE inhibitors *[Guideline]*.

The combination of hydralazine and nitrates in addition to ACE inhibitors, beta-blockers and diuretics is recommended for patients self-described as African Americans who have moderate-to-severe symptoms. This combination has resulted in significant benefit to the group in randomized controlled trials *[Guideline]*.

Digoxin improves symptoms for patients in sinus rhythm with ventricular dilatation, elevated filling pressures and a third heart sound *[High Quality Evidence]*, *[Moderate Quality Evidence]*, *[Low Quality Evidence]*.

Digitalis improves symptoms, exercise tolerance and quality of life but neither increases nor decreases mortality *[High Quality Evidence]*. Digoxin significantly increased ventricular ejection fraction compared to both placebo and captopril. It also decreased hospitalizations and treatment failure compared to placebo *[Moderate Quality Evidence]*. The ACC/AHA 2009 Guideline Focused Update lists digitalis as beneficial in heart failure patients with reduced left ventricular ejection fraction (LVEF) to decrease hospitalizations for HF-Class IIa Level B *[Guideline]*.

Finally, diuretics should be used, in the smallest doses necessary, to control fluid retention. Care should be taken to avoid hypokalemia, hypomagnesemia, prerenal azotemia, or orthostatic hypotension. Diuretic doses may need to be reduced in order to introduce or optimize

treatment with ACE inhibitors and beta-blockers. Aldosterone antagonists have been shown to reduce mortality. Addition of an aldosterone antagonist is recommended in selected patients with moderately severe to severe symptoms of HF and reduced LVEF who can be carefully monitored for preserved renal function and normal potassium concentration. Creatinine should be 2.5 mg per dL or less and potassium should be less than 5.0 mEq per liter. Under circumstances where monitoring for hyperkalemia or renal dysfunction is not anticipated to be feasible, the risks may outweigh the benefits of aldosterone antagonists. An ARB or isosorbide/hydralazine combination can be considered in patients intolerant to ACE inhibitors *[Guideline]*.

Treatment of Heart Failure with Preserved Ejection Fraction

In contrast to the treatment of heart failure due to reduced LVEF, few clinical trials are available to guide the management of patients with heart failure and relatively preserved LVEF. For the management of patients with HFPEF, it is particularly important to address the underlying etiology. Ischemia and hypertension must be optimally controlled. Pericardial disease must be specifically treated if present. Control of atrial tachyarrhythmias may be of particular importance since these patients need adequate time for diastolic filling, and they poorly tolerate tachycardia. Beta-blockers may be of value to slow the heart rate and allow a longer time interval for diastolic filling.

In general, drugs used to treat systolic dysfunction (ACE, ARBs, diuretics, beta-blockers) are used in patients with heart failure with preserved systolic function but indicated to manage comorbidities *[Low Quality Evidence]*.

Patients with hypertrophic cardiomyopathy should be identified and may benefit from genetic counseling. Patients with hypertrophic cardiomyopathy may benefit from beta-blockers to slow heart rate. Some may benefit from verapamil or disopyramide if beta-blockers are not effective. In cases of significant intracavitary pressure gradients, dual chamber pacing or septal myectomy surgery may be indicated. Particular attention must be given to the control of atrial tachyarrhythmias. Care should be taken to avoid venodilators and arterial vasodilators.

For patients with predominant HFPEF:

Treat specific contributing causes:

- Hypertension (goal is blood pressure of less than 130/80 mmHg) *[Guideline]*
- Ischemic heart disease
- Hypertrophic cardiomyopathy – consider referral to subspecialist (for verapamil, disopyramide, surgical myectomy, pacemaker)
- Constrictive pericarditis

See Table 4, "New York Heart Association Functional Classification and Treatment," in the original guideline document. See also Annotation #13, "Pharmacologic Management," below.

12. Treat Secondary Causes of Heart Failure and Significant Comorbid Conditions and Risk Factors
Recommendations

- Beta-blockers and digoxin should be used either alone or in combination for achieving rate control in atrial fibrillation in heart failure.
- Blood transfusions are not recommended to treat anemia in heart failure.
- Intravenous iron replacement may improve anemia symptoms specifically the six-minute walk test.

Treat as indicated by the particular disease state. Specific treatment modalities for secondary causes of HF are considered outside of the scope of this guideline. See Tables 1 and 2 in the original guideline document.

Atrial Fibrillation (AF) in Heart Failure

Several studies have been done in patients with heart failure and AF that will influence management of this arrhythmia *[Moderate Quality Evidence]*. Patients with heart failure are at increased risk for atrial fibrillation and constitute an important subgroup of all patients with this arrhythmia. AF affects 10% to 30% of patients with chronic heart failure. Atrial fibrillation may be a marker of poor prognosis, in which the primary problem is poor ventricular function, neurohormonal activation, or inflammation, with no independent effect of atrial fibrillation on outcome.

The control of ventricular rate and the prevention of thromboembolic events are essential elements of treatment of heart failure in patients with an underlying supraventricular arrhythmia. Beta-blockers and digoxin used either alone or in combination are the drugs of choice for achieving rate control. Digoxin is effective in controlling ventricular rate at rest, but may not achieve satisfactory rate control with exertion. Amiodarone may be added to beta-blockers and/or digoxin if adequate rate control is not achieved. Of anti-arrhythmics used in patients with heart failure with reduced ejection fraction and AF, only amiodarone and dofetilide do not effect survival adversely *[Moderate Quality Evidence]*.

Cardiorenal Syndrome

No interventions based on proposed mechanisms of the development of cardiorenal syndrome (CRS) have shown consistent advantage, and the work group does not have any specific recommendations. However, developing awareness, the ability to identify and define, and physiological understanding will help improve the outcome of these complex patients.

A large proportion of patients with the syndrome of heart failure have concurrent heart and renal dysfunction. The "cardiorenal syndrome" has been classified *[Low Quality Evidence]*. The development and progression of renal failure is a strong independent predictor of long-term adverse outcome in patients with congestive heart failure. The overall understanding of the pathogenesis of cardiorenal syndrome is limited. Cardiorenal syndrome can be generally defined as a pathophysiologic disorder of the heart and kidneys whereby acute or chronic dysfunction of one organ may induce acute or chronic dysfunction of the other. The characterization and classification of this syndrome may provide ideas for the testing of hypotheses regarding the pathogenesis of this syndrome and help in designing interventions for the management of cardiorenal syndrome.

Anemia: Workup and Treatment for Iron Deficiency in Patients with Heart Failure

The prevalence of iron deficiency in congestive heart failure ranges from 5% to 21% and may be related to malabsorption, long-term aspirin, uremic gastritis, or reduced iron recycled in the reticuloendothelial system *[Low Quality Evidence]*. Heart failure guidelines suggest that the correction of anemia has not been established as routine heart failure therapy, and more specifically, that blood transfusions are not recommended to treat the anemia of chronic disease in heart failure *[Low Quality Evidence]*, *[Guideline]*. It is unclear whether anemia is the cause of decreased survival or a marker of more severe disease in heart failure patients. Intravenous iron replacement for iron deficiency in heart failure patients with or without anemia has been shown to improve symptoms of heart failure, specifically an improvement in the six-minute walk test with an increase of 40 meters from baseline at 24 weeks of therapy and improvements in quality-of-life assessments *[Moderate Quality Evidence]*. The death rate and serious adverse event rate are not significantly improved. Other treatments including oral iron replacements *[Systematic Review]*, erythropoiesis stimulating agents (ESAs), and blood transfusions have not shown proven benefit.

Refer to the original guideline for more information.

13. Pharmacologic Management
    Recommendations

- Carvedilol, metoprolol succinate (extended release), and bisoprolol have demonstrated reductions in mortality for patients with all classes of heart failure, so use these agents before using other generic beta-blockers.
- ACE inhibitors should be prescribed for all patients with left ventricular systolic dysfunction unless specific contraindications exist. An elevated baseline creatinine is not a specific contraindication.
- In non-African Americans, ACE inhibitors are recommended for decreasing heart failure mortality than the isosorbide dinitrate/hydralazine combination. In contrast, combining hydralazine and nitrates is recommended for patients self-described as African Americans, with moderate-severe symptoms on optimal therapy with ACE inhibitors, beta-blockers, and diuretics.
- ARBs should be considered primarily for patients who are intolerant of ACE inhibitors or those receiving standard drug therapy (including ACE inhibitors) who continue to show clinical deterioration.
- Routine use of ARBs with ACE inhibitors and aldosterone antagonists cannot be recommended.
- Diuretics should not be the sole therapy for patients with signs of volume overload, and vasoactive drugs should be considered.
- In severe heart failure use loop diuretics over thiazide diuretics and combination therapy with thiazide (or thiazide-like medication). Loop diuretics are also effective in refractory cases of volume overload.
- In patients with NYHA Class III-IV heart failure on stable doses of digoxin and ACE inhibitors, reduce mortality by administering aldosterone-blocking agents (spironolactone, eplerenone).
- Currently, the work group recommends that nesiritide be reserved for patients with acutely decompensated heart failure who remain volume overloaded despite aggressive treatment with diuretics/vasodilators, display tolerance and/or resistance to vasodilators or diuretics, or demonstrate significant side-effects to other vasodilators.
- When considering the use of calcium channel blockers (CCBs) in heart failure patients, only dihydropyridine CCBs such as amlodipine and felodipine have been shown to be safe. However, non-dihydropyridines such as diltiazem and verapamil, can be used in patients with preserved systolic heart failure *[Low Quality Evidence]*.

Refer to the original guideline document for more information on non-dihydropyridine and dihydropyridine CCBs.

Aldosterone	Role in Heart Failure

antagonists
 	
(Eplerenone, spironolactone)
	Aldosterone antagonists reduce mortality and hospitalizations in patients with heart failure.
	
	Clinical Indication(s)
	
	Patients with heart failure symptoms (NYHA class II-IV) and an EF ≤35% who are already on standard therapies (ACE inhibitors, beta-blockers, diuretics and digoxin).
	
	Regardless of the underlying mechanism(s) of benefit, and given the results of EMPHASIS-HF *[High Quality Evidence]*, aldosterone-receptor antagonists should be prescribed to patients with NYHA class II symptoms, LVEF less than 30% (or wide QRS for those with LVEF 30% to 35%), and cardiovascular hospitalization within six months or evidence of elevated natriuretic peptide levels in the absence of contraindications *[Low Quality Evidence]*.
	
	Lab Monitoring
	
	• Potassium and BUN/creatinine:
	  • Baseline
	  • Three to seven days after initiation
	  • Every month for the first three months
	  • Quarterly thereafter
	• The above lab monitoring cycle should be restarted after dosage increases and when initiating medications that interact with spironolactone/eplerenone.

Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)	Role in Heart Failure
	
	ACE inhibitors reduce morbidity, mortality and hospitalizations in patients with heart failure.
	
	Clinical Indication(s)
	
	ACE inhibitors are indicated for patients with all stages of heart failure (NYHA I-IV) when the EF has dropped below 40%.
	
	Lab Monitoring
	
	• Potassium and BUN/creatinine:
	  • One to two weeks after initiation/dose increases (one week recommended in the elderly)
	  • Three to four weeks after initiation
	  • Thereafter, one to two times per year
	• The above lab monitoring cycle should be restarted after dosage increases and when initiating other medications which increase creatinine/potassium.

Angiotensin Receptor Blockers (ARBs)	Role in Heart Failure
	
	ARBs reduce morbidity, mortality and hospitalizations in patients with heart failure.
	
	Clinical Indication(s)
	
	ARBs should be primarily utilized in patients who meet the criteria for ACE-inhibitor use (NYHA class I-IV, EF <40%) but who cannot tolerate ACE-inhibitor therapy.
	
	Lab Monitoring
	
	• Potassium and BUN/creatinine:
	  • One to two weeks after initiation/dose increases (one week recommended in the elderly)
	  • Three to four weeks after initiation
	  • Thereafter, one to two times per year
	• The above lab monitoring cycle should be restarted after dosage increases and when initiating other medications that increase creatinine/potassium.

Beta-Blockers	Role in Heart Failure Beta-blockers reduce mortality, hospitalizations and improve symptoms in patients with heart failure.

	Clinical Indications Beta-blockers are indicated for stable, symptomatic (NYHA class II and III) patients with an EF <40%) and heart failure that is of ischemic, hypertensive or cardiomyopathic origin. Most beta-blocker studies have been done in patients already taking an ACE inhibitor, diuretic and (in some cases) digoxin. For rate control in tachycardia-induced heart failure, the work group prefers beta-blockers over other agents. If the patient is limited by symptoms of orthostatic hypotension with carvedilol, consider a change to metoprolol succinate to allow titration to goal heart rate.
Digoxin	Role in Heart Failure Digoxin reduces symptoms, hospitalizations and improves exercise capacity in patients with heart failure. Digoxin does not have an effect on heart failure mortality. Clinical Indications Digoxin has been found useful in mild-moderate systolic (EF <40%) heart failure patients with atrial fibrillation with a rapid ventricular response, and in combination with ACE inhibitors in reducing hospitalizations *[High Quality Evidence]*. Lab Monitoring • Digoxin blood levels: Digoxin levels are typically recommended in patients with 1) five to seven days after starting therapy/dosage change/starting therapy with known interactions, 2) suspected toxicity, 3) suspected non-adherence, 4) new or existing renal dysfunction, and/or 5) determining whether patient is in the therapeutic range. • Serum creatinine and electrolytes: Generally recommended at baseline and then periodically thereafter.
Hydralazine/Nitrates	Role in Heart Failure Hydralazine given with isosorbide dinitrate has been shown to provide symptomatic and mortality benefits in patients with systolic heart failure. Clinical Indications • Hydralazine/nitrates is indicated for those patients with moderate to severe heart failure symptoms (NYHA class III-IV heart failure, EF <40%), who are already taking ACE inhibitors (or ARBs), beta-blockers and diuretics. • Hydralazine/nitrates can also be used IN PLACE of an ACE inhibitor/ARB in those patients who cannot tolerate either therapy.

Loop Thiazide Diuretics	Role in Heart Failure
	
	• Diuretics are helpful in reducing the signs and symptoms of fluid overload (e.g., edema, dyspnea) associated with heart failure.
	• Diuretics have yet to demonstrate a reduction in morbidity/mortality associated with heart failure. It is therefore recommended that diuretics not be the sole therapy used to treat heart failure.
	Lab Monitoring
	
	• Sodium, Potassium, Chloride/Bicarbonate, BUN/Serum creatinine (basic chemistry panel)
	  • Before diuretic initiation
	  • During the diuretic initiation phase, the first lab after starting therapy is dependent on the degree of diuresis:
	  • Outpatients on oral diuretic therapy should have their labs repeated once approximately five to seven days after diuretic initiation. If lab abnormalities are present, labs should be repeated weekly until they have stabilized.
	  • Inpatients on large intravenous doses of diuretics (including drips) or who require frequent dose changes should have labs repeated daily at a minimum.

	• Following the initiation phase, stable outpatient diuretic patients should have a basic chemistry panel drawn every four months for the duration of therapy. If any of the following occurs, lab monitoring will need to be more frequent until the patient stabilizes:
	  • Changes in diuretic dose, route or frequency
	  • The patient's condition worsens
	  • The patient develops signs/symptoms of electrolyte abnormalities
	• If lab abnormalities are found at any time, increased lab surveillance is warranted until levels have normalized.
	• Magnesium, Calcium
	  • Before diuretic initiation, then every four months for the duration of therapy
	Glucose Checks (diabetic patients)
	  • Before diuretic initiation
	  • During the initiation phase (the first week of therapy), the glucose checks should be increased above baseline to ascertain the effect of the diuretic on glucose trends
	  • Following the initiation phase, stable outpatient diuretic patients should follow their normal glucose monitoring. If any of the following occurs, glucose checks will need to be more frequent until the patient stabilizes:
	  • Dose/route/frequency changes
	  • The patient's condition worsens
	  • The patient develops signs/symptoms of electrolyte abnormalities
	• Uric Acid
	  • Patients without active gout or a history of gout do not need uric acid levels unless signs/symptoms of gout are present.
	  • Patients with gout or a history of gout should have a uric acid level drawn:
	  • Before diuretic initiation
	  • One week after the diuretic is initiated and annually thereafter
	  • If any of the following occurs, uric acid levels will need to be more frequent until the patient stabilizes:
	  • Changes in diuretic dose, route, or frequency
	  • The patient's condition worsens
	  • The patient develops signs/symptoms of worsening gout
	  • If lab abnormalities are found at any time, increased lab surveillance is warranted until levels have normalized.

BUN, blood urea nitrogen; EF, ejection fraction; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; Scr, serum creatinine

Refer to the original guideline document for more information including adverse events and supporting literature associated with these medications, and to the "Contraindications" field for contraindications for these medications.

14. Non-pharmacologic Management
    - Engage the patient in his or her care and include shared decision-making between patient, family and the physician.
      Shared decision-making is a process in which patients and clinicians collaborate to clarify all acceptable options, ensure the patient is well-informed, and choose a course of care consistent with patient values and preferences, and the best available medical evidence.

      Please refer to Appendix C, "ICSI Shared Decision-Making Model," in the original guideline document.

    - All patients with heart failure should receive dietary instruction regarding sodium intake since dietary indiscretion is the most common cause of exacerbation of heart failure.
    - Provide dietary counseling for patients to learn the need for fluid balance management, avoiding excess sodium and/or water intake. Refer to a dietitian for patients with comorbid conditions or repeat episodes of edema. Sodium restriction alone may provide substantial benefits for heart failure patients.
    - Patients should call their clinician for a two-pound or greater weight gain overnight or a five-pound or greater weight gain in a week. Daily weights are important for managing heart failure and early detection of increases in fluid retention.
    - Simplifying medication regimes as much as possible should be explored. All medications, including over the counter (OTC)

medications should be reviewed at each visit.

- Patients should be assessed for depression. Major depression is common in patients hospitalized with heart failure and is independently associated with a poor prognosis. Additionally, depression is independently associated with a substantial increased risk of heart failure in older patients with isolated systolic hypertension.
- Consider utilizing a heart failure clinic or case management for patients with medical problems or at high risk for re-hospitalization.
- Exercise instruction should be included as part of a comprehensive heart failure program *[Systematic Review]*.

Patient education for early symptom recognition and counseling about the disease process should be initiated at this time. See the Implementation Tools and Resources Table section in the original guideline document for Web sites and tools to assist the clinician and patient with non-pharmacologic management of heart failure.

Refer to the original guideline document for additional information on dietary recommendations, daily weights, medications, vaccinations, exercise and activity guidelines, phase 3 cardiac rehabilitation, smoking cessation, hospital discharge and reducing hospital readmissions, transitional care, heart failure management programs, telemonitoring programs, stress reduction, depression, advanced directives, and end-of-life considerations.

15. Symptom Control Satisfactory?
    Recommendation:

    - Consider reassessment of ventricular function (echocardiography or radionuclide ventriculography) if the symptoms persist despite changes in pharmacologic management or if symptoms markedly change.

16. Consider Specialty Referral
    Recommendations:

    - Primary care clinicians should continue to be involved in the decision-making process when subspecialty consultation and management are necessary.
    - Communication between the primary caregiver and the cardiologist is key and should be encouraged even before the need for a referral in order to integrate seamless diagnostic and therapeutic care.

    Once it has been determined that the patient is a candidate for revascularization, the next step is angiography performed by a cardiologist. Subspecialty consultation will generally involve not only performance of the procedure, but also recommendations for further management. Primary care clinicians should continue to be involved in the decision-making process. Primary care clinicians should also be familiar with risks associated with various patterns of disease distribution seen on angiogram. The decision to proceed with revascularization must be determined on an individual basis. Consultation should take place among the patient, primary care clinician, cardiologist, and cardiovascular surgeon to determine the most appropriate course of action.

    If the results of the angiogram do not show significant CAD or if the decision is made not to proceed with revascularization, pharmacologic management should be continued (see Annotation #13, "Pharmacologic Management").

    Refer to the original guideline document for information on surgical procedures (cardiac resynchronization therapy [CRT]; implantable cardioverter defibrillator [ICD]; left ventricular assist devices; continuous infusions of positive inotropic agents such as dobutamine, dopamine, or milrinone; palliative care and hospice; and when to consider referral to subspecialist.

17. Ongoing Assessment of Response to Treatment and Evaluation for Symptom Exacerbation
    Recommendations

    - After initial evaluation and diagnosis, follow-up of heart failure patients in the ambulatory setting should focus on optimizing pharmacologic therapy and prevention of heart failure exacerbations.
    - Patient education should be ongoing and consistently reinforced, and family members should be a part of this process whenever possible. Symptoms of worsening heart failure should be explained, and patients should be advised to contact their clinician or nurse if these symptoms develop.
    - Patients should be advised to call their clinician about a greater than or equal to two pounds/day weight gain or five or more pounds/week. They can expect the clinician to assess symptoms, adjust diuretics if appropriate, discuss dietary sodium compliance/restriction, review treatment plan, and recommend appropriate level of care (office visit, ED, etc.).
    - Also refer to Appendix B, "Strategies to Address Adherence to Treatment Plan," in the original guideline document.

    Accessibility

    Intimidation by or frustration with large health care systems and social isolation are factors that distance patients from their health care clinicians. A patient's failure to maintain this contact, as well as inadequate patient education, contributes to poor patient compliance and high

hospital admission and readmission rates in this population *[Low Quality Evidence]*, *[Moderate Quality Evidence]*.

> - To prevent heart failure exacerbation, efforts and resources should be directed toward early intervention in the form of increased accessibility to care and education aimed at symptom recognition and treatment plan adherence.
> - Frequently, patients wait until they are in crisis before seeking medical assistance, bypassing the clinician's office and going straight to the ED. Limited hours and limited/untrained staff at clinician' offices have been cited as reasons patients seek acute care with worsening symptoms of heart failure.
> - Case managers and heart failure clinics have been shown to be effective strategies to avert ED visits and hospitalizations by providing patients with a contact person who is familiar with their care to expedite treatment alternatives. This contact person, usually a nurse, is available to answer questions and clarify instructions, potentially increasing treatment plan compliance. The nurse should have adequate ancillary support services available (e.g., social workers, dietary)
>   - A mid-level clinician can provide an appropriate level of care adjusting medications and dosages.
>   - NTproBNP has been shown to be useful in determining the long-term prognosis of patients with congestive heart failure. After hospital admission the euvolemic/dry BNP value at discharge can be used as a meaningful and valuable baseline level for subsequent monitoring and management of patients with heart failure.
> - Time between visits is important for the patient to formulate questions and assimilate the previously presented information. Family members and care givers should also be involved in education to support the patient's efforts.
>
> *[Moderate Quality Evidence]*, *[Low Quality Evidence]*

Definitions:

Crosswalk between ICSI Evidence Grading System and GRADE System

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Design of Study Current ICSI System		ICSI GRADE System
Class A:	Randomized, controlled trial	High, if no limitation
		Moderate, if some limitations
		Low, if serious limitations
Class B:	[observational]	
	Cohort study	High, if well done with large effect
		Moderate, if well done with effect
		Low, most studies
Class C:	[observational]	
	Non-randomized trial with concurrent or historical controls	
	Case-control study	Low
	Population-based descriptive study	Low
	Study of sensitivity and specificity of a diagnostic test	Low*
*Following individual study review, may be elevated to Moderate or High depending upon study design.		
Class D:	[observational]	
	Cross-sectional study	Low
	Case series	

Design of Study Concept	Current ICSI System	ICSI GRADE System
Class M:	Meta-analysis	Meta-analysis
	Systematic review	Systematic review
	Decision analysis	Decision analysis
	Cost-effectiveness analysis	Cost-effectiveness analysis
Class R:	Consensus statement	Low
	Consensus report	Low
	Narrative review	Low
	Guideline	Guideline
Class X:	Medical opinion	Low
Class Not Assignable		Class Not Assignable

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

Clinical Algorithm(s)

A detailed and annotated clinical algorithm titled "Heart Failure in Adults" is provided in the original guideline document .

Scope

Disease/Condition(s)

Heart failure

Other Disease/Condition(s) Addressed

- Anemia
- Atrial fibrillation

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Cardiology

Emergency Medicine

Family Practice

Geriatrics

Internal Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Emergency Medical Technicians/Paramedics

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To decrease the readmission rate for patients 18 years and older with heart failure diagnosis, within 30 days of discharge following hospitalization for heart failure
- To increase the rate of heart failure patients 18 years and older who receive optimum evidence-based pharmacologic treatment with heart failure
- To improve the use of diagnostic testing in order to identify and then appropriately treat adult patients with heart failure
- To increase the rate of heart failure patients age 18 years or older who have comprehensive patient education and follow-up care

Target Population

Adult patients age 18 years and older with suspected heart failure

Interventions and Practices Considered

Diagnosis/Evaluation

1. Initial evaluation/history and laboratory tests, including complete blood count, urinalysis, renal and liver function
2. Early triage to determine level of care, emergency or inpatient
3. Use of the Framingham criteria tool
4. Echocardiogram or radionuclide scintigraphy
5. Reevaluation of persistent or recurrent symptoms

Treatment/Management

1. Pharmacological treatment/management
    - Beta-blockers (e.g., carvedilol, metoprolol succinate, bisoprolol)
    - Angiotensin-converting enzyme (ACE) inhibitors
    - Digoxin
    - Digitalis
    - Diuretics, in smallest dose necessary
    - Combination therapy (e.g., hydralazine and nitrates in addition to ACE inhibitors, beta-blockers, and diuretics)
    - Angiotensin receptor blockers (ARBs), as indicated
    - Calcium channel blockers
    - Aldosterone antagonists
    - Hydralazine/nitrates
    - Treatment by specific contributing cause: hypertension, ischemic heart disease, cardiomyopathy
2. Non-pharmacologic management
    - Shared decision-making
    - Dietary recommendations (sodium restriction, fluid management, alcohol intake, dietary supplements and vitamins)
    - Daily weight monitoring
    - Medication review and management
    - Patient education
    - Vaccination
    - Exercise and activity guidelines: phase 3 cardiac rehabilitation
    - Smoking cessation
3. Transitional care
4. Telemonitoring programs
5. Stress reduction
6. Depression assessment and treatment
7. End-of-life considerations, including advance directives
8. Specialty referral

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Hospitalization rates
- Morbidity and mortality
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses and other literature (stage II). Literature search terms used for this revision include brain natriuretic peptide, Framingham criteria for heart failure, preventable hospital readmission in heart failure, spironolactone, observation units for heart failure patients, and Society of Chest Pain and the American College of Cardiologists guidelines from January 2011 through January 2013.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Following a review of several evidence rating and recommendation writing systems, the Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE System

Design of Study Current ICSI System		ICSI GRADE System
Class A:	Randomized, controlled trial	High, if no limitation
		Moderate, if some limitations
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	Case series	
	Case report	
Class M:	Meta-analysis	Meta-analysis
	Systematic review	Systematic review
	Decision analysis	Decision analysis
	Cost-effectiveness analysis	Cost-effectiveness analysis
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Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

New Guideline Development Process

A workgroup consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and

an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups, hospitals, or other organizations that are not members of ICSI. Patients on occasion are invited to serve on work groups.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 24 months as indicated by changes in clinical practice and literature. For documents that are revised on a 24-month schedule, ICSI checks with the work group on an annual basis to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled. For yearly reviewed documents, ICSI checks with every work group 6 months before the scheduled revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Literature Search

ICSI staff, working with the work group to identify any pertinent clinical trials, systematic reviews, or regulatory statements and other professional guidelines, conducts a literature search.

Revision

The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined in the "Description of Method of Guideline Validation" field.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Document Approval

Each document is approved by the Committee for Evidence-Based Practice (CEBP).

The committee will review and approve each guideline/protocol, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included.
- The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.
- The link between the recommendation and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.
- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for *health care systems* to support implementation of the document.
- The document is supported with practical and useful tools to ease *clinician* implementation.
- Where local resource availability may vary, alternative recommendations are clear.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment and management of patients with heart failure

Potential Harms

Adverse events associated with medications (see the original guideline document for details)

Contraindications

Contraindications

Contraindications to aldosterone antagonists include:

- Renal dysfunction (creatinine >2.5, glomerular filtration rate [GFR] <30 mL/min) and/or significant impairment of renal excretory function
- A recent increase in serum creatinine >25%
- Hyperkalemia (potassium >5)

Contraindications to angiotensin-converting enzyme (ACE) inhibitors include:

- History of intolerance or adverse reactions to these agents including angioedema, persistent cough and/or rash
- Serum potassium greater than 5.5 mEq/L
- Symptomatic hypotension (unless due to excessive diuresis)
- Severe renal artery stenosis
- Pregnancy

Contraindications to angiotensin receptor blockers (ARBs) include:

- History of intolerance or adverse reactions to these agents including angioedema and/or rash
- Serum potassium greater than 5.5 mEq/L
- Symptomatic hypotension (unless due to excessive diuresis)
- Severe renal artery stenosis
- Pregnancy

Contraindications to beta-blockers include:

- Severe bradycardia
- Sick sinus syndrome (unless pacemaker in place)
- Second- or third-degree heart block
- Cardiogenic shock
- Decompensated heart failure
- Known allergic reaction

Contraindications to digoxin include:

- Ventricular fibrillation
- Known hypersensitivity to digoxin

Contraindications to loop thiazide diuretics include anuria and existing allergic reaction to the active diuretic component.

Contraindications to hydralazine/nitrates include:

- *Hydralazine* is contraindicated in patients with hypersensitivity to hydralazine and mitral valvular rheumatic heart disease.
- *Nitroglycerin* is contraindicated in patients with hypersensitivity to nitroglycerin and in those patients who are currently using a phosphodiesterase-5 (PDE-5) inhibitor. This combination has been shown to potentiate the hypotensive effects of nitrates.

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs, and behaviors of the organization

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Develop a process that will allow primary care providers to identify patients who have been re-admitted to the hospital with a diagnosis of heart failure.
- Emphasize patient self-management strategies. These may include heart failure education and other actions designed to sustain engagement of patients with their heart failure care.
- Develop a process to provide education to the patient and/or caregiver in the area of:
    - Diet
    - Weight monitoring (to include: clinician should be contacted about a two-pound or greater weight gain overnight or a five-pound or greater weight gain during the week)
    - Activity level
    - Medications
    - The importance of follow-up appointments
    - What to do if symptoms worsen
- Develop a process for timely, early specialty referral for patients with ischemia or those who are refractory despite optimal medical therapy.

Implementation Tools

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Heart failure in adults: percentage of patients with heart failure diagnosis and LVSD who at the last clinic visit met the following (if eligible): prescribed or were on ACEI/ARB, prescribed or were on beta-blocker therapy, and a non-smoker.

Heart failure in adults: percentage of patients with heart failure diagnosis who were educated on the management of their condition.

Heart failure in adults: percentage of patients with heart failure diagnosis who have a follow-up appointment with their primary care clinician within seven days of hospital discharge.

Heart failure in adults: percentage of heart failure patients who are current smokers or tobacco users who received smoking cessation advice or counseling in primary care.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

End of Life Care

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Pinkerman C, Sander P, Breeding JE, Brink D, Curtis R, Hayes R, Ojha A, Pandita D, Raikar S, Setterlund L, Sule O, Turner A. Heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jul. 94 p. [190 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1997 Oct (revised 2013 Jul)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of 50+ medical group and hospital members representing 9,000 physicians in

Minnesota and surrounding areas, and is sponsored by five nonprofit health plans. For a list of sponsors and participating organizations, see the ICSI Web site .

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline. The annual dues of the member medical groups and sponsoring health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Committee on Evidence-Based Practice

Composition of Group That Authored the Guideline

Work Group Members: Charles Pinkerman, MD (*Work Group Leader*) (Park Nicollet Health Services) (Cardiology); Paul Sander, MD (*Work Group Leader*) (North Memorial Health Care) (Cardiology); Joshua E. Breeding, PharmD, BCPS (Fairview Health Services) (Pharmacist); Shama Raikar, MD (HealthPartners Medical Group and Regions Hospital) (Internal Medicine); Oghomwen Sule, MD (Howard Young Medical Center) (Internal Medicine); Ashok Ojha, MD (Hutchinson Medical Center) (Internal Medicine); Rochelle Curtis, PA (Park Nicollet Health Services) (Cardiology); Deepti Pandita, MD (Park Nicollet Health Services) (Internal Medicine); Angela Turner, PA-C (Park Nicollet Health Services) (Cardiology); Darin Brink, MD (University of Minnesota Physicians) (Family Medicine); Rochelle Hayes, BS (Institute for Clinical Systems Improvement) (Systems Improvement Coordinator); Linda Setterland, MA, CPHQ (Institute for Clinical Systems Improvement) (Clinical Systems Improvement Facilitator)

Financial Disclosures/Conflicts of Interest

The Institute of Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at the ICSI Web site .

Disclosure of Potential Conflicts of Interest

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National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Family Medicine, University of Minnesota Physicians

National, Regional, Local Committee Affiliations: None
Guideline Related Activities: Colorectal Cancer Screening Guideline Work Group
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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National, Regional, Local Committee Affiliations: Minneapolis Heart Institute
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: Breast Cancer Treatment Guideline Work Group
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: Chronic Obstructive Pulmonary Disease
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: Diagnosis and Initial Treatment of Stroke
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

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Guideline Availability

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The following is available:

- Heart failure in adults. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2013 Jul. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Patient Resources

None available

NGC Status

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